Purged by D. Dries 3/18/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207
Telephone: 313-226-6260

WARNING LETTER
98-DT-07

MAR 16 1998

William Lichtenberger
Chief Executive Officer
Praxair, Inc.
39 Old Ridgebury Road
Danbury, CT 06810-5113

Dear Mr. Lichtenberger:

Investigator Patsy Domingo and Analyst Steve Senio inspected Praxair Distribution, Inc. 12820 Evergreen Detroit, MI from January 28- February 3, 1998. They found the firm to be operating with significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulations, Parts 210 and 211].

Oxygen USP, Nitrogen NF, Nitrous Oxide USP, Helium USP, Compressed Air USP and Carbon Dioxide USP are drugs within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (The Act).

Your medical gases are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of the products are not in conformance with 21 CFR 210 and 211. Violations encountered during the inspection include, but are not limited to, the following:

Failure to establish that the test procedure used to determine the strength and identity of Helium USP and Carbon Dioxide, USP will provide test results that are equivalent or superior to the official test procedure. [21 CFR 211.165(e)].

Failure to establish that the test procedures used to determine the impurities in medical gases will provide results that are equivalent or superior to the official test procedure. [21CFR 211.165(e)]

Failure to document the proper maintenance of the [redacted] Oxygen Analyzer used in the assay of Oxygen, USP and Nitrogen NF. [21 CFR 211.194(d)]

Failure to adequately document training provided to plant personnel who perform tests. [21 CFR 211.25]

The Medical Air, USP manufactured by this firm is misbranded within the meaning of Sections 502(a) and 502(g) of the Act.

Compressed Air, USP [Medical Air, USP] bears the statement Oxygen USP 21% Nitrogen NF 79%. Compressed Air is manufactured not by combining Oxygen and Nitrogen, but with an air compressor.

Compressed Air, USP purports to be a drug the name of which is recognized in the official compendia, but is not packaged and labeled as prescribed therein.

We acknowledge receipt of Mr. J.M. Hercik, Quality Assurance Specialist, Medical Gas Products February 23, 1998 letter. It will be made a permanent part of the firm's establishment file. The corrective action detailed will be assessed during the next scheduled inspection. We would like to offer the following comments:

Nitrogen NF can be analyzed with an oxygen analyzer provided that the supplier of Nitrogen is registered with FDA, a valid Certificate of Analysis is received with each delivery, the filling system has dedicated lines and supplier audits are performed. Nitrous Oxide USP can be analyzed with the pressure differential test, however, the identity test must be performed concurrently.

The subject firm's sources of Helium and Carbon Dioxide are Praxair facilities, which are not registered with FDA. Industrial grade gas should not be used as a drug product. All drugs must be manufactured in accordance with Current Good Manufacturing Practices in registered facilities.

The above violations are not meant to be an all inclusive list of deficiencies in your operation. It is your responsibility to assure that your firm's products adhere to the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

Please update this office in writing within 15 working days of the receipt of this letter of any additional steps you have taken to correct these violations and to prevent their recurrence.

We realize that Praxair Distribution, Inc. and Praxair, Inc. have multiple locations. This letter is an official notification that FDA expects all Praxair locations to be in compliance. All of your locations should be assessed and corrective action taken corporate wide if deficiencies exist. Your response should be directed to the attention of Mrs. Judith A. Putz, Compliance Officer, U.S. Food & Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207 (Telephone 313-226-6260 ext. 137).

Sincerely yours,

John V. Dempster for

Raymond V. Mlecko
Acting District Director
Detroit District

CC:
James W. Chilcoff, General Manager
Praxair Distribution, Inc.
12820 Evergreen Road
Detroit, MI 48223

Jack Hercik, Quality Assurance Specialist
Praxair Distribution, Inc.
7261 Engle Road Suite 306
Middleburg Heights, Ohio 44130